Use of a care bundle to reduce mortality following emergency laparotomy

Emergency laparotomy is a common intra-abdominal procedure with outcomes recognized to be poor. Efforts are being made to improve these outcomes, both nationally and internationally. This article describes the methodology of a successfully implemented collaborative quality improvement project that improved outcomes following emergency laparotomy in four NHS trusts.

Many clinicians participate in competitive sport or exercise (e.g. running, cycling, golf). Most understand that to improve their performance they must look at specific parts of their technique, make small adjustments, try new ways of training or use new equipment. Improvements are measured, and further alterations are then made and retested.

Similarly, who would start assembling a new piece of equipment without looking at the instructions or making a complex dish without a recipe? Adherence to a protocol is associated with better outcomes (i.e. a functioning piece of equipment or a palatable meal). However, how many doctors use these principles of small incremental improvements and protocol-delivered care in their work place to improve patient outcomes in a similar way?

The quote 'the definition of insanity is doing the same thing over and over again and expecting different results' is widely credited to Einstein. We seem to understand this idea when we consider training for a sports event but until recently have ignored it when trying to improve the mortality rate from emergency laparotomy.

The results of a collaborative quality improvement project for patients undergoing emergency laparotomy (Emergency Laparotomy Pathway Quality Improvement Care (ELPQuiC) bundle) have recently been published (Huddart et al, 2015). The project ran over 8 months in four general hospitals in England and showed a 25% reduction in crude 30-day mortality and a 38% reduction in risk-adjusted hospital mortality rate. A simple care bundle was used (*Figure 1*) to ensure that patients who required emergency laparotomy were treated by the right people, using the best evidence available as quickly as possible.

The background to conceiving, planning and implementing this collaborative quality improvement project has not been described. This article describes the methodology used to achieve this success.

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Quality improvement

The model for improvement was first described by Langley et al (2009). This simple model lays the basis for a systematic approach to quality improvement in any area of activity from marathon training to emergency laparotomy.

The model for improvement has three key questions that need to be addressed before a systematic effort is made to improve a specific outcome (*Figure 2*):

1. What are we trying to achieve (setting aims)?
2. What changes can we make that will result in improvement (selecting changes and generating new ideas and approaches)?
3. How will we know that a change is an improvement (selecting measurements)?

Following these three questions multiple Plan-Do-Study-Act (PDSA) cycles are performed. In simple terms these involve planning a change or improvement, introducing the change, seeing what effect it has, and then responding to that change.

This process allows different changes to be introduced and lessons learnt from these changes. Too often in medicine, an improvement is introduced that does not work immediately and the project then falls flat on its face. The PDSA cycle allows testing

Figure 1. The ELPQuiC bundle.

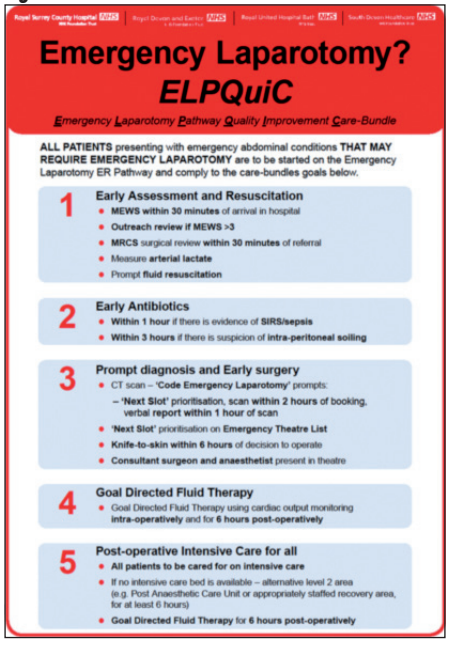
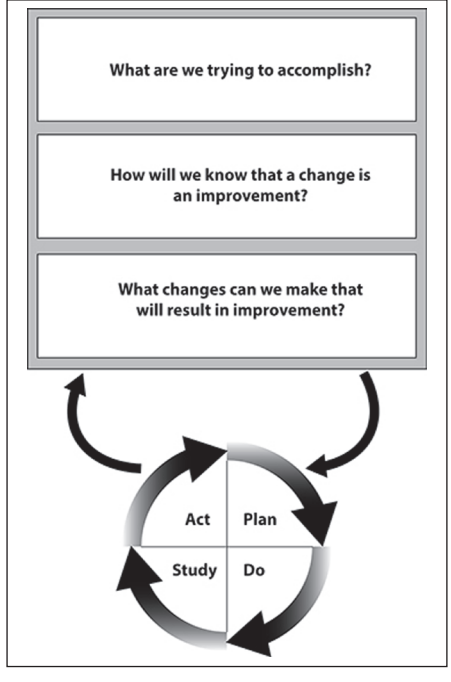


Figure 2. Plan-Do-Study-Act cycle.



and failure (or success), and then refinement. Over a period of time, the best solution to a problem is identified and becomes part of standard practice or performance.

A useful template to think through the elements that are likely to make quality improvement projects successful is that described in the breakthrough series developed by the Institute for Health Improvement (2003) as a companion to the model for improvement. This series identifies a number of features that should be considered when initiating a change programme, which are:

1. Select a topic
2. Recruit expert faculty to identify evidence-based changes required
3. Enrol participating organizations
4. Use learning sessions to engage stakeholders and spread knowledge
5. Action periods. This allows participating organizations to introduce new ideas and methods as part of a PDSA model for assessing the effect of changes.

When planning improvement in the care of patients undergoing emergency laparotomy both the 'model for improvement' and the 'breakthrough series' were used throughout the ELPQuiC project. The first three questions from the model for improvement focused thinking, while the breakthrough series features enabled the team members to plan, share ideas to accelerate improvement and carry out the project.

What are we trying to achieve?

The first Confidential Enquiry into Perioperative Deaths report was published in 1987 (Buck et al, 1987). This report, and many subsequent reports from the National Confidential Enquiry into Patient Outcome and Death, highlighted the poor standard of care offered to patients undergoing emergency laparotomy (Findlay et al, 2011).

In 2006 Pearse and colleagues published a retrospective review of outcomes in over four million surgical patients (Pearse et al, 2006). They identified a subset of patients who had a surprisingly high mortality rate. These patients were often elderly, had significant pre-existing comorbidity and were admitted to hospital as emergency cases. Almost 80% of all surgical deaths could be accounted for in this subgroup.

More recently the NHS Emergency Laparotomy Network study was carried out. Thirty-five hospitals voluntarily contributed data from almost 2000 patients over a 3-month period. The results showed a wide variation in unadjusted 30-day mortality between 3.6% and 41.7% (Saunders et al, 2012). The report also highlighted the wide variation in delivery of key aspects of care, most notably consultant involvement, use of 'goal-directed' fluid resuscitation, and the use of intensive care facilities in the immediate postoperative period.

This last publication identified to each participating hospital its own mortality rate and performance on key metrics. It became clear that improvement was required.

'What we are trying to achieve', or the 'aim' was identified as a reduction in 30-day (and in-hospital) mortality rate for patients undergoing emergency laparotomy.

What changes can we make that will result in improvement?

Emergency laparotomy is a complex clinical problem. From first presentation in the emergency department or ward, patients frequently develop sepsis or hypovolaemia or both. Patients need rapid resuscitation, treatment of sepsis, diagnostics and access to emergency operating theatres. The patient moves through a variety of departments and is seen by a wide range of medical and nursing staff.

Fortunately there is significant high quality evidence available that should help improve outcomes for patients undergoing emergency laparotomy:

Early warning score

The use of a simple scoring system (early warning score) to identify patients at an early stage before organ damage and injury occurs (National Institute for Health and Care Excellence, 2007).

Surviving Sepsis guidelines

The publication of the Surviving Sepsis Campaign guidelines in 2004 identified the need to resuscitate patients and administer antibiotics as soon as possible (Dellinger et al, 2004). Evidence showed that the more reliably and quickly the 'resuscitation' aspect of the Surviving Sepsis Campaign guidelines was delivered the better the outcomes for patients with sepsis (Gao et al, 2005; Levy et al, 2015). The guidelines emphasize the need for rapid source control to allow optimal outcomes (Dellinger et al, 2004, 2013).

Preventing delay to starting treatment

Evidence both from the Surviving Sepsis Campaign guidelines and reports from the Royal College of Surgeons of England suggests that delays to the start of definitive treatment will increase the risk of poor outcomes (Royal College of Surgeons of England, 2011; Royal College of Surgeons of England and Department of Health, 2011; Royal College of Surgeons of England and Association of Surgeons of Great Britain and Ireland, 2013).

Use of cardiac output monitors

The use of non-invasive cardiac output monitors has been recommended by the National Institute for Health and Care Excellence (2011). Strong evidence suggests that in high risk surgical patients complication and mortality rates are significantly decreased (Pearse et al, 2005; Cecconi et al, 2013). In addition it is now recognized that the occurrence of any complication in the postoperative period is probably one of the most important predictors of both in-hospital and longer-term survival (Khuri et al, 2005).

Admissions to the intensive care unit

Admitting patients to the intensive care unit after major surgery has less strong direct evidence. Over 60% of patients undergoing emergency laparotomy have a mortality risk (Portsmouth physiological and operative severity score for the enumeration of morbidity and mortality (P-POSSUM)) of 5% or more (ELPQuiC database, unpublished data, April 2011–July 2013). The emergency laparotomy network data (Saunders et al, 2012) showed that all patients aged over 60 years of age and all those classified as American Society of Anesthesiologists grade III or more had greater than 10% mortality.

Much of this evidence and further recommendations for standards of care were brought together in *The Higher Risk General Surgical Patient* (Royal College of Surgeons of England and Department of Health, 2011) and *Emergency Surgery. Standards for Unscheduled Surgical Care* (Royal College of Surgeons of England, 2011).

The body of information available is extensive and many recommendations are available. However, to carry out this col-

laborative project a care bundle approach was used. Care bundles use a small number (ideally no more than five) of evidence-based key steps that each work synergistically to achieve the desired goal (Resar et al, 2012). The care bundle developed is shown in *Figure 1*.

How will we know that a change is an improvement?

The primary outcome was 30-day mortality; secondary outcomes included hospital mortality and postoperative length of stay.

The ELPQuiC care bundle was agreed. Data on an additional two measurements were also collected (involvement in the operating theatre of a consultant surgeon and anaesthetist) as these were thought to represent best standard of care.

Some of the metrics of the care bundle were easy to measure, such as admission to intensive care unit or the use of intraoperative goal-directed fluid therapy. Others were more difficult, such as timing of the administration of antibiotics when sepsis or visceral perforation was suspected and the time from deciding to carry out surgery to the entry of patients into the operating theatre. In addition it was decided to use the completion of an early warning score (or equivalent) at initial assessment as the definition of the presence of an escalation process aimed at identifying and treating the most unwell patients.

For each of the care bundle metrics, factors that might alter the ability to deliver the desired change were considered. Probably the most complex of the five bundle elements was ensuring patients were operated on within 6 hours of booking theatres. To help understand this process a driver diagram technique was used (*Figure 3*) (Peden, 2011). This technique attempts to identify, diagrammatically, what factors may contribute (or hinder) the delivery of a specific goal. From this diagram several secondary measures were chosen to identify the ability deliver the bundle element, e.g. time to computed tomography scan was measured to ensure delay to the operating theatre was not caused by this part of the process.

Team set up and management

Once the initial care bundle was developed and measurements decided, partner hospitals were sought. The use of several hospitals over a wide geographical area allowed quicker acquisition of patient numbers and sharing of different approaches. In addition, achieving transformation across several hospitals would provide increased external validity for the study.

Each hospital had to meet specific requirements:

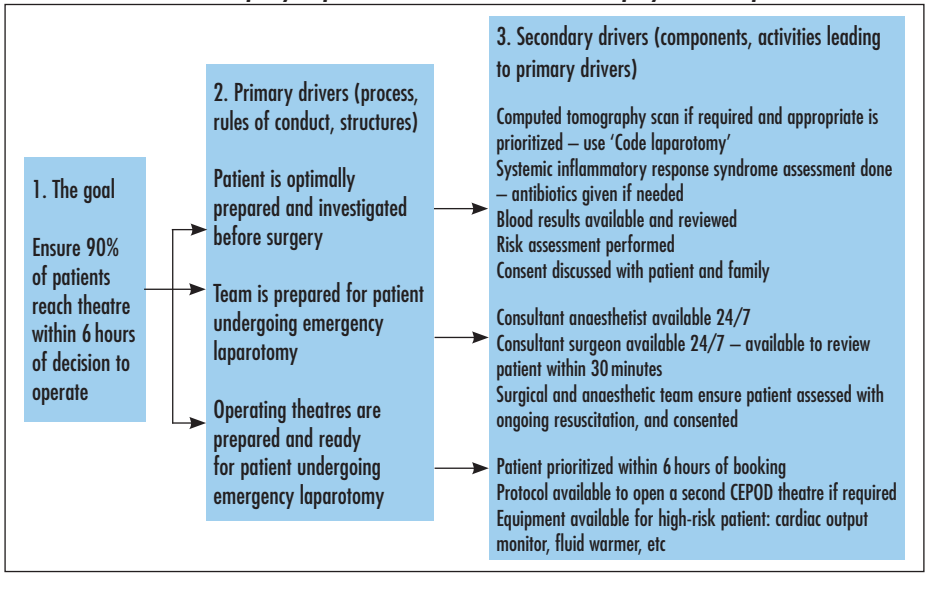
1. Executive buy-in and agreement from the hospital's medical director or chief executive
2. The appointment of a lead for the project and the formation of a multidisciplinary team consisting of surgeons, anaesthetists, intensive care doctors, nurses and other interested personnel
3. The appointment of a part-time data post to ensure accurate and contemporaneous data collection.

Each hospital had its own unique model of care for emergency laparotomies. Each hospital was asked to consider what areas of the care bundle it was already delivering to the majority of patients presenting for emergency laparotomy. Hospitals were then asked to identify methods for improving compliance with areas of the care bundle where poor compliance existed. Some hospitals were well organized in their ability to deliver early warning score-activated escalation and the delivery of antibiotics to appropriate patients. Others struggled to offer goal-directed fluid therapy in theatres or to admit patients to the intensive care unit after surgery.

In order to identify particular strengths and weakness a series of run charts and other performance charts were produced every 6 weeks from contemporaneous data. These run charts incorporated statistical process control techniques. Statistical process control is a branch of statistics that combines time series analysis methods with graphical presentation of data, often yielding insights into the data more quickly than that produced by comparative studies, and in a way more understandable to decision makers (Benneyan et al, 2003). An example of how statistical process control was used is shown in *Figures 4–6*. The whole project team from all four hospitals met every 4–6 weeks to consider these charts. This offered an opportunity for shared learning of effective methods for changing staff attitudes and process of care. At these meetings, each project team was asked to report on how the project was progressing and to identify techniques that they had found useful in delivering change.

Each team organized their own quality improvement cycles. This often involved teaching and education (e.g. use of goal-directed fluid management systems). There were also alterations to protocols for instance, access to operating theatre departments or prioritizing computed tomography scan for patients who were likely to require emergency laparotomy.

Figure 3. Driver diagram for a systematic approach to ensure patients reach theatre within 6 hours of the decision to operate. 90% was chosen as the goal, as any quality improvement programme will acknowledge that there will always be patient exceptions. The aim should be to ensure that the goals are reached for the vast majority of patients. CEPOD = Confidential Enquiry into Perioperative Deaths.



In addition each team lead met with other colleagues around the hospital to assist in the quality improvement project. This included general surgeons, the intensive care, emergency department and radiology teams. Some hospital teams met regularly with general surgeon and anaesthetic colleagues to highlight specific cases where care had either been well provided or where discussion about further improvements was considered necessary.

Learning points

Each hospital found different techniques useful to improve the quality of care for patients undergoing emergency laparotomy. Examples include:

- The use of a specific patient care plan that allowed patients who presented with acute abdominal pain to be managed with one document. This document included early warning score, P-POSSUM scores, relevant blood and physiological results, patient clerking details and timing of specific events such as time of antibiotics and wait for admitting to emergency operating theatres
- Use of a 'boarding card' information sticker that carried key details required to deliver a patient quickly through the system. This included details such as whether or not sepsis screening had been performed and a space for a pre-operative P-POSSUM score to be recorded for risk assessment. Sepsis management stickers that prompt rapid diagnosis and management of severe sepsis were also used in some centres
- Protocol ('code laparotomy') for prioritizing computed tomography scanning, access to emergency theatres and intensive care
- Regular meeting with key leaders within the hospital to gauge delivery. This included lead clinicians from medicine, emergency department, radiology and intensive care. 'Winning the argument' was crucial at this level to allow these leaders to then change the behaviour of their own teams
- Attendance at regular morbidity and mortality meetings, presenting up-to-date outcome data, was an important way of changing 'hearts and minds' of consultant surgeons and their teams.

Figure 4. Statistical process control run chart showing time from decision to theatre in hours for all consecutive inclusive cases before and after introduction of ELPQuiC.

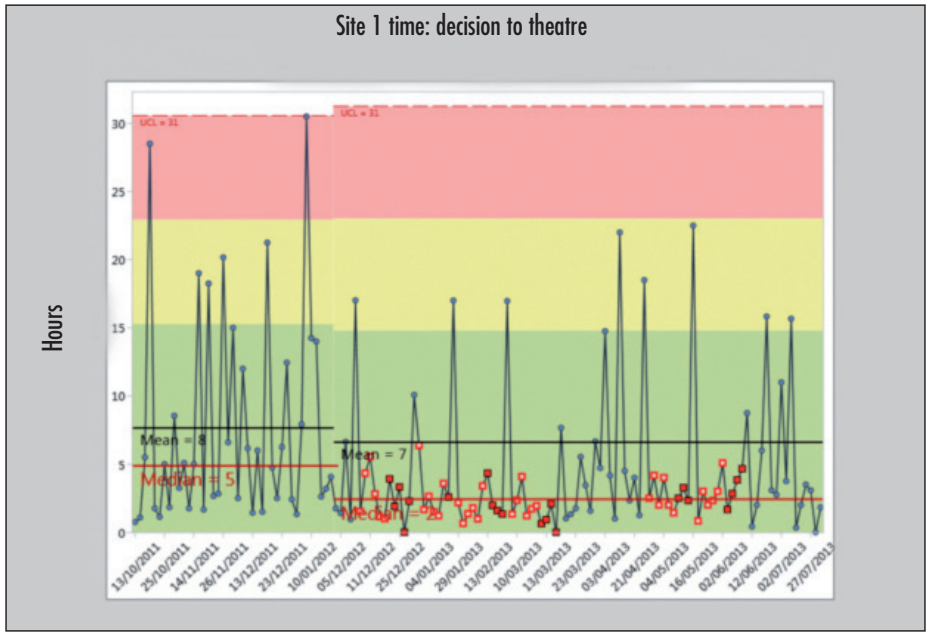
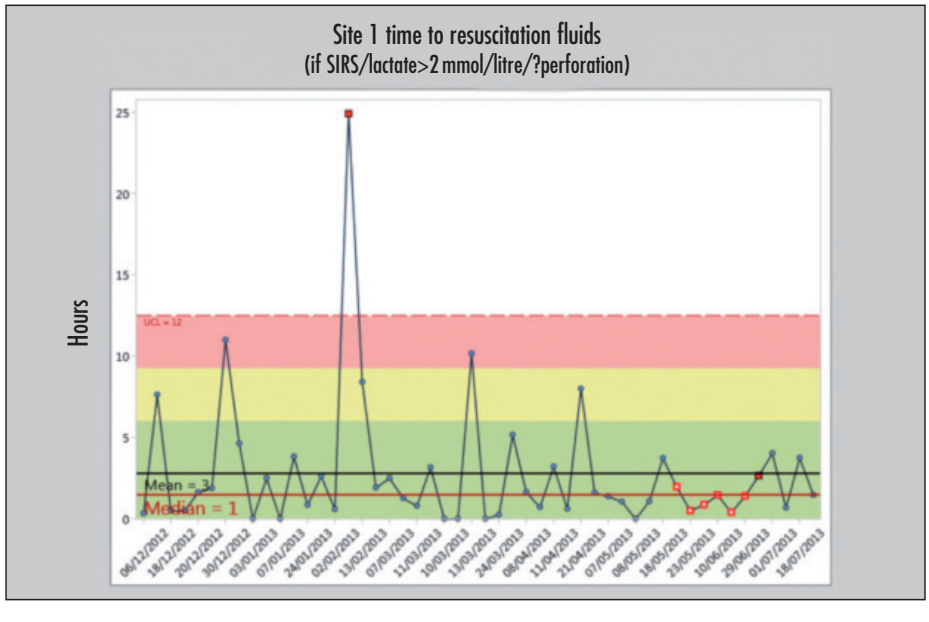


Figure 5. Statistical process control run chart showing time from clinical deterioration to resuscitation fluids for patients presenting with systemic inflammatory response syndrome (SIRS) and/or suspected peritoneal soiling and/or lactate >2 mmol/litre (in hours for consecutive inclusive cases after introduction of ELPQuiC only).



Conclusions

Mortality from emergency laparotomy can be dramatically reduced. The use of a care bundle technique can help this process. Ongoing data from the four hospitals involved in this collaborative project suggest continued reduction in mortality rates for patients undergoing emergency laparotomy. Realizing that this is the new standard of care may be one aspect of the continued delivery of the care bundle. In addition 'making quality healthcare easy' must also feature as part of the explanation of the ongoing success of this pathway.

The Institute of Heath Improvement asks the question 'do you have the will, ideas and ability to execute the delivery of your ideas?' (Nolan, 2007). In order to improve outcomes for patients undergoing emergency laparotomy new ways of thinking, use of evidence-based medicine and an ability to implement change will be required. BJHM

Figure 2 *is reproduced from www.ihi.org/resources/Pages/HowtoImprove by kind permission of the Institute for Healthcare Improvement.*

Conflict of interest: Dr N Quiney has received travel expenses from LIDCO PLC, London (manufacturers of cardiac output monitors) to give a lectures at several international conferences; Dr S Huddart, Professor C Peden and Dr M Dickinson: none.

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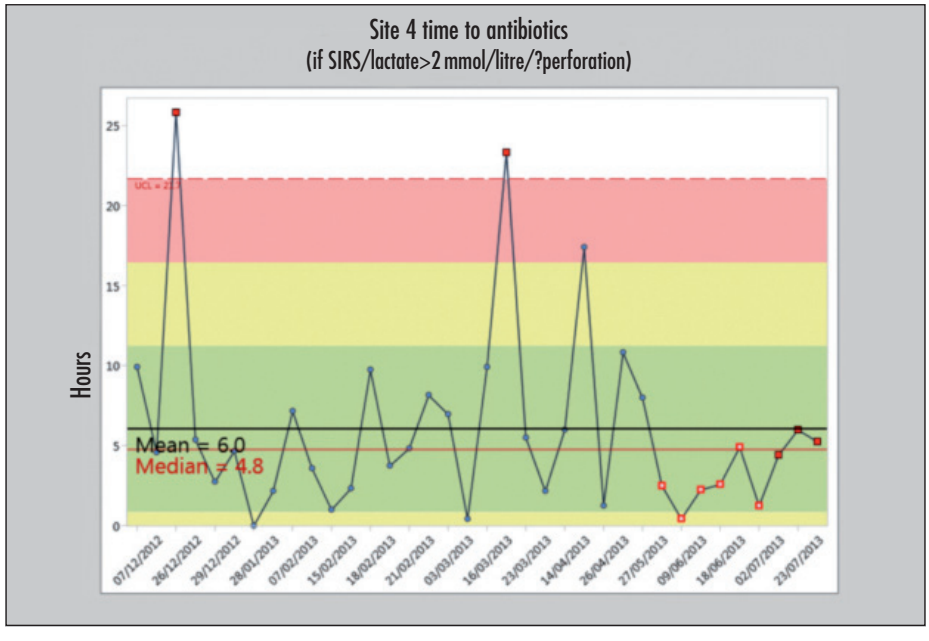
Figure 6. Statistical process control run chart showing time from clinical deterioration to antibiotics for patients presenting with systemic inflammatory response syndrome (SIRS) and/or suspected peritoneal soiling and/or lactate >2 mmol/litre (in hours for consecutive inclusive cases after introduction of ELPQuiC only).



LEARNING POINTS

- Emergency laparotomy is a complex clinical problem. Heterogeneous pathological processes and patient pathways present challenges to improving outcomes.
- Addressing the three key questions from the model for improvement and then performing multiple Plan-Do-Study-Act (PDSA) cycles provides a systematic framework for quality improvement projects.
- Combining evidence-based medicine with quality improvement techniques has improved outcomes in the emergency laparotomy population.